Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of Core stability exercises with Otago exercises on balance and quality of life in patients with stroke

Protocol summary

Study aim
Determining and Comparing the Effect of Central Stability Exercises with Otago Exercises on Balance and Quality of Life in Patients with Stroke

Design
Clinical trial with control group, with parallel, blinded, randomized, 69 patients

Settings and conduct
By the Ethics Committee on University Research. At the beginning of the study, demographic questionnaires, leaf equilibrium, time-to-go test, and quality of life questionnaire for stroke were completed. Then, after the intervention, leaf balance questionnaire and time-to-go test were completed and the quality of life questionnaire for stroke was completed one month after completion of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age range 40 to 70 years 2. Neurologist diagnoses ischemic stroke 6 months after stroke 4. Patient balance with cut-off score of 32 and below based on leaf balance questionnaire 5. Individual time 14 ≤ seconds in the timed take-and-go test 6. Ability to walk independently 7. Having the physical ability to participate in exercise based on the opinion of a specialist 8. No Comorbidities (Heart, Pulmonary and Mental Disorders) 9. Consent to participate in the study and sign the informed consent form 10. Patient's previous non-participation in studies similar to current research Exclusion criteria: 1. Research participants can be excluded from the study under any circumstances.

Intervention groups
The three intervention groups consisted of central stabilization exercises, Otago exercises and control groups. In the Central Stability and Otago Exercises group, there are eight sessions of exercise for eight weeks, three times a week, and 5 minutes of cooling off after each session. The control group received no training.

Main outcome variables
Balance and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200107046046N1**
Registration date: **2020-03-21, 1399/01/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-21, 1399/01/02**
Update count: **0**

Registration date
2020-03-21, 1399/01/02

Registrant information

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Fatemeh Pirayesh

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of Core stability exercises with Otago exercises on balance and quality of life in patients with stroke

Public title
Comparison of the Effect of Central Stability Exercise and Otago Exercise on Stroke

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Neurologist diagnoses ischemic stroke 6 months after stroke Patient balance with cut-off score of 32 and below based on leaf balance questionnaire Individual time 14 ≤ seconds in the timed test of getting up and going Ability to walk independently Having the physical ability to participate in exercise based on the opinion of a specialist No Comorbidities (Heart, Pulmonary and Mental Disorders) Consent to participate in the study and sign the informed consent form No previous patient participation in studies similar to current research Age range 40 to 70 years

Exclusion criteria:
Research participants can be excluded from the study at any time.

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **69**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible individuals were randomly assigned based on the lottery method in which the number of individuals in each group was placed in a numbered container and randomly selected at the time of referral and divided into 3 groups for exercise. Central stability, auto-training and control will be provided.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Yasuj University of Medical Sciences

Street address
Yasuj, Shahid Motahari Blvd., Yasuj University of Medical Sciences

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Approval date
2020-02-22, 1398/12/03

Ethics committee reference number
IR.YUMS.REC. 1398. 162

Health conditions studied

1

Description of health condition studied
Patients with stroke

ICD-10 code
G46.4

ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1

Description
Balance

Timepoint
Balance at baseline (before intervention) and after baseline

Method of measurement
Berg balance scale (BBS)

2

Description
Quality of life

Timepoint
Quality of life at baseline (before intervention) and one month after baseline

Method of measurement
Stroke Specific Quality Of Life (SSQOL)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Core stability exercises: Includes Gestures: Camel Cat (lean on your hands and knees on the ground. Rotate your back with your abdominal muscles and pelvis held steady. Then let your waist down as you lift your chest up. And arches), four arms and legs (raising one leg and one arm and one leg), cobra (sleeping on the abdomen and placing your head on your hands and lifting your head upwards and then lowering your chest) Lift up to the hip), lying on the back (raising one leg, raising one foot to the side of the hand and then the opposite hand, raising the pair of legs, raising the pair of legs with two hands and raising the pair of legs). With the ball), hamstring stretches on the chair and on the ground, crunch (flat foot, regular, reverse and ball), bridge (assisted and unassisted) and bridging the Swiss ball They will do three sessions per week for eight weeks and will complete a 5 minute cool down after each session.

Category
Rehabilitation

2

Description
Intervention group: Otago exercises: Includes gestures: walking forward (with and without support), heel (with and then without support), lateral walking (with and without support), single leg (with and without support) Backing), getting up from the chair (with two hands, one hand, no hands and with the ball), walking backwards (with backing and then unsupported and finally with the ball), heel walking (with backing and then Unsupported and ultimately with the ball), they walk and rotate around, doing three sessions for eight weeks each week, and doing 5 minutes of cooling down after each session.

Category
Rehabilitation

3

Description
Control group: Non-intervention: This group will not be trained.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Fatemeh Pirayesh
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Shahid Beheshti Hospital, Shahid Mohammad Montazeri Street, Yasuj
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Fatemeh Pirayesh
Position
MSc Student of Internal Surgery Nursing
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available